GP-1636

FISH & RICHARDSON P.C.

Frederick P. Fish
1855-1930

W.K. Richardson
1859-1951

225 Franklin Street
Boston, Massachusetts
02110-2804

Telephone
617 542-5070

Facsimile
617 542-8906

Web Site
www.fr.com

August 6, 2002

Bronwen M. Loeb, Ph.D.
Patent Examiner
U.S. Patent and Trademark Office
Art Unit 1636
Washington, DC 20231

COPY OF PAPERS
ORIGINALLY FILED

FR

BOSTON
DALLAS
DELAWARE
NEW YORK
SAN DIEGO
SILICON VALLEY
TWIN CITIES
WASHINGTON, DC

Re: ANDROGEN RECEPTOR COMPLEX-ASSOCIATED PROTEIN
Serial No.: 09/781,693
Filing Date: February 12, 2001
Inventors: Tai-Jay Chang
Our Ref.: 11709-003001

Dear Examiner Loeb:

Further to our telephone conversation of Friday, August 2, 2002 enclosed please find a copy of the office action dated July 28, 2002 issued in error against the above-referenced serial number.

Should you have any questions regarding this matter, please do not hesitate to contact me.

Very truly yours,

Y. Rocky Tsao

Y. Rocky Tsao

YRT/drn
Enclosure

20486146.doc

YRT
YJL

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,893	01/17/2001	Shih-Chieh Hung	11709-003001	6011

7590 07/28/2002

Eric L. Prahl
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804

EXAMINER
LOEB, BRONWEN

ART UNIT	PAPER NUMBER
1636	8

DATE MAILED: 07/28/2002

09/761,893

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/761,893	HUNG ET AL.	
	Examiner	Art Unit	
	Bronwen M. Loeb	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-11 and 21-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11 and 21-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This action is in response to the amendment filed 1 April 2002 in which claims 1 and 4-7 were amended, claims 8 and 12-20 were cancelled and new claims 21-31 were presented.

Claims 1-7, 9-11 and 21-31 are pending.

Oath/Declaration

1. The objection to the declaration has been withdrawn as the alteration made was to the date of an Inventor's signature, which alteration does not render the declaration defective.

Response to Amendment

2. The rejection of claims 4-11 under 35 U.S.C. §112, second paragraph, as being indefinite has been withdrawn in view of Applicant's amendment.

The rejection of claims 2, 3 and 8 under 35 U.S.C. §102(b) as being anticipated by Lucas et al (Wound Repair and Regeneration (1995) 3:449-460) is withdrawn as reconsideration of this art made it clear it did not anticipate these claims as it did not teach a porous plate in the culture device.

The rejection of claims 2, 3 and 8 under 35 U.S.C. 103(a) as being unpatentable over Lucas et al in view of Bruder et al (USP 5,942,225) has been withdrawn in view of Applicant's amendment.

3. Claims 1, 4, 5, 7, 9 and 10 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lucas et al (Wound Repair and Regeneration (1995) 3:449-460).

Claims 1, 4-7, 9, 10, 11, and new claim 30, stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lucas et al in view of Bruder et al (USP 5,942,225).

4. New grounds of rejection, necessitated by Applicant's amendment, are presented below.

Response to Arguments

5. With regard to the rejection of claims 1, 4, 5, 7, 9 and 10 under 35 U.S.C. §102(b) as being anticipated by Lucas et al, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that Lucas et al does not teach "seeding" mesenchymal stem cells but rather teaches filtering mesenchymal stem cells through a device. This argument is not persuasive. Lucas et al teaches culturing a mixture comprising mesenchymal stem cells by plating the mixture and culturing the cells. The instant specification does not define "seeding" and it is therefore given its common meaning in interpreting the claims, that is, inoculating cells into a culturing device. Therefore the instant invention reads on the method of plating taught by Lucas et al. The rejection is maintained.

6. With regard to the rejection of claims 1, 4-7, 9, 10, 11, and new claim 30, under 35 U.S.C. 103(a) as being unpatentable over Lucas et al in view of Bruder et al (USP

5,942,225), Applicant's argument have been fully considered but are deemed not persuasive.

Applicant argues that Lucas et al is a deficient reference and that Bruder et al does not make up for the deficiency. As discussed above, Lucas et al is not deficient. Bruder et al was cited to illustrate the well-known use of DMEM-LG to culture mesenchymal stem cells. Therefore this argument is not persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-7, 9-11 and 21-31 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in lacking a step which clearly refers back to the preamble. The recited steps lead to a culturing of mesenchymal stem cells however the preamble recites "a method for recovering mesenchymal stem cells".

Claim 25 is vague and indefinite in reciting improper Markush group language. There are two "ands" recited whereas there should only be one. See MPEP 2173.05(h).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, 7,9, 21, 22, 25 and 27 are rejected under 35 U.S.C. §102(b) as being anticipated by Rieser et al (WO 97/46665; USP 6,242,247 is the national stage equivalent to WO 97/46665 and is referenced in the following as it is in English). Rieser et al teach a method of making implants comprising culturing cells capable of chondrocyte-function, including mesenchymal stem cells (MCS), in a culture device comprising a porous plate. The plate has pores in the range of 2 to 20 microns. Rieser et al demonstrate their method using cells obtained from bovine shoulder (therefore mammalian tissue). The cells thus cultured can differentiate into cartilage. Note that the preamble of the instant claims does not provide a patentable distinction when the recited steps may stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Thus, while Rieser et al do not teach recovering mesenchymal stem cells, this limitation is no longer recited in the steps of the amended claim. See entire document, especially the Abstract, col. 5, lines 15-19, col. 7, lines 7-11 and col. 8, lines 7-9.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(e), (f) or (g) prior art under 35 U.S.C. §103(a).

13. Claims 1-7, 9, 11, 21, 22, 24-27, 29 and 30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Rieser et al in view of Bruder et al (USP 5,942,225). Rieser et al is applied as above to claims 1-5, 7,9, 21, 22, 25 and 27. Rieser et al do not teach the method wherein the mixture comprising MCS is human, or that MSC are cultured in DMEM-LG. At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use mammalian MSC in the method taught by Rieser et al, or to culture the MSC in DMEM-LG. One would have been motivated to do either of these as DMEM-LG is a well-known culture medium for MSC and is advantageous in providing selective attachment for MSC. One would be motivated to obtain human

MSC because of their great therapeutic value in various human pathologic conditions such as hematological cancers, and for use in bone repair and cartilage replacement. See, for instance, Bruder et al (col. 1, lines 8-12, col. 3, lines 42-54 and col. 5, lines 4-40).

Conclusion

Claims 1-7, 9-11 and 21-31 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

July 26, 2002

REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice of References Cited

Application/Control No.	Applicant(s)/Patent Under Reexamination	
09/761,893	HUNG ET AL.	
Examiner	Art Unit	Page 1 of 1
Bronwen M. Loeb	1636	

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-6,242,247 B1	06-2001	Rieser et al	---
X	B	US-5,942,225	08-1999	Bruder et al	---
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 97/46665 A1	12-1997	WIPO	Rieser et al	---
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.